



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2012-N-1258]

Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities
(Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability;
Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document that we made available for public comment by notification in the Federal Register of January 16, 2013. We are taking this action to make the comment period for the draft RA conform to the comment period for proposed rules entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (the proposed preventive controls rule) and “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the proposed produce safety rule). Elsewhere in this issue of the Federal Register, we are announcing a 120-day extension of the comment period for the proposed preventive controls rule and the proposed produce safety rule.

DATES: The comment period for the document published January 16, 2013, at 78 FR 3824, reopened March 13, 2013, at 78 FR 15894, is extended. Submit either electronic or written comments by September 16, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3824), we published a notification with a 30-day comment period announcing the availability of, and requesting comment on, a document entitled “Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.” The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. Interested persons were originally given until February 15, 2013, to comment on the draft RA.

We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. In the Federal Register of January 16, 2013 (78 FR 3824), we announced that we had used the results of the

draft RA to propose to exempt certain food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until May 16, 2013, to comment on the proposed preventive controls rule.

We previously received requests to allow interested persons additional time to comment on the draft RA. Two requesters had considered that the comment period for the draft RA should conform to the comment period of the proposed preventive controls rule. (One of these requesters further requested that the comment period conform to that of the proposed produce safety rule, which published in the Federal Register of January 16, 2013 (78 FR 3504), and other major rulemakings that we would be conducting under FSMA but were not yet published.) We considered the requests and reopened the comment period for the draft RA until May 16, 2013-- i.e., the same date as that for the proposed preventive controls rule and the proposed produce safety rule (Federal Register of March 13, 2013, 78 FR 15894).

We have now received comments requesting an extension of the comment period on the proposed preventive controls rule and the proposed produce safety rule. Each request conveyed concern that the current 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to those proposed rules. We have considered the requests and, elsewhere in this issue of the Federal Register, we are granting a 120-day extension of the comment period for those proposed rules. We are extending the comment period for the draft RA for 120 days to continue to make the comment period for the draft RA conform to the comment period for the proposed preventive controls rule and the proposed produce safety rule.

II. Request for Comments

Interested persons may submit either electronic comments regarding the draft RA to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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